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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/684,452

10/15/2003

Elisco Quintanilla Almagro

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05/25/2006

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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT

PAPER NUMBER

1655

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/684,452

Applicant(s)

QUINTANILLA ALMAGRO ET AL.

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/856,035.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 0304.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-12, in the reply filed on 14 April 2006 is acknowledged.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Deshpande et al. (Cancer Letters, 1997) or by Kuttan et al. (Cancer Letters, 1986).

A method for treating a mammal susceptible to a condition associated with a proliferative disease comprising administering to said mammal an effective amount of at least one *Curcuma* extract is claimed.

Deshpande et al. teach a method for treating tumors - i.e., forestomach tumors (which clearly read upon a condition associated with a cell proliferative disease - i.e., the formation of tumors) in mice via administering one of various *Curcuma longa* (also known as turmeric) rhizome extracts thereto, whereby the extracts (e.g., a water-extract and/or an ethanol extract thereof) are administered in amounts effective to significantly reduce and inhibit tumor formations (see entire document including, e.g., Abstract, Materials and Methods, Table 1, and Discussion).

Kuttan et al. also teach a method for treating tumors - i.e., lymphoma tumors (which clearly read upon a condition associated with a cell proliferative disease - i.e., the formation of tumors) in mice via administering a *Curcuma longa* (also known as turmeric) rhizome extract

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thereto, whereby the extract (e.g., aqueous ethanolic extract thereof) is administered in amounts effective to significantly reduce and inhibit tumor formations (see entire document including, e.g., Abstract, Materials and Methods, Table 2, and Discussion).

Please note that, as drafted, the claims are not limited to a mammal having a condition associated with a proliferative disease, but instead to a mammal susceptible to a condition associated with a proliferative disease. Since mice (as well as all mammals) are susceptible to one or more conditions associated with a proliferative disease (including those characterized by an increase in cytokine production such as increased IL-8 or IL-6 production, as well as the various conditions recited in claim 12), the administered mice disclosed by each of the cited references meet this claim limitation - as drafted (including with respect to prophylactic/preventative treatment thereof).

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Claims 1, 5, and 9-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Shah (US 5,693,327).

Shah teaches a method for treating various conditions associated with a proliferative disease including some of those instantly claimed (e.g., psoriasis and lichen planus - please note that such conditions are inherently characterized by an increase in IL-6 and/or IL-8 cytokine production) via administering to a human or non-human animal in need thereof a composition comprising an effective amount of a *Curcuma longa* and/or *Curcuma aromatica* aqueous extract therein (see entire document including col 1, line 4 - col 2, line 55; col 4, line 39 - col 5, line 29; col 7, lines 5-6; and claims).

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Therefore, the reference is deemed to anticipate the instant claims above.

Claims 1 and 5-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Quintanilla Almagro et al. (ES 2103689 - including full English translation thereof).

The cited reference teaches a method of treating (augmenting) one or more conditions associated with a proliferative disease in a mammal (humans) via administering to the mammal one or more (aqueous and/or ethanolic) extracts from *Curcuma longa* rhizomes (which, as readily admitted by Applicants reads upon the instantly claimed extract - see, e.g., paragraph [0049] of the instant specification) - see entire English translation including pages 9-26, Figures, and claims thereof. Further, again please note that, as drafted, the claims are not limited to a mammal having a condition associated with a proliferative disease, but instead to a mammal susceptible to a condition associated with a proliferative disease. Since mammals including humans are susceptible to one or more conditions associated with a proliferative disease (such as those characterized by an increase in cytokine production such as increased IL-8 or IL-6 production, as well as the various conditions recited in claim 12), the administered mammals (humans) disclosed by the cited reference meet this claim limitation - as drafted (including with respect to prophylactic/preventative treatment thereof).

Therefore, the reference is deemed to anticipate the instant claims above.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. (Cancer Letters, 1997), Kuttan et al. (Cancer Letters, 1986), and Paek et al. (Arch. Pharm. Res., 1996), in view of Otsuka et al (JP 11151309 - including DWPI Abstract and full JPO computer-assisted English translation).

The Deshpande et al. and Kuttan et al. references are relied upon for the reasons set forth above. Neither of these two references expressly teaches treating other cancers such as leukemia therewith.

Paek et al. beneficially teach the effective use of an anti-tumor *Curcuma longa* rhizome extract in treating human leukemia cells *in vitro* (so as to induce cell death) - see entire document including, e.g., Abstract, Methods, Figures, Results and Discussion.

None of the above references teaches the further use of radiation for such cancer treatment.

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Otsuka et al. beneficially teach the use of a light radiation device to selectively suppress (treat) the propagation of cancer cells in a subject, whereby the device selectively radiates visible light - preferably in the range of 430-530 nanometers, via administering the light radiation to the those portions of the subject's body having cancerous cells (see DWPI Abstract and full JPO computer-assisted English translation).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a *Curcuma longa* rhizome extract (including an aqueous and/or ethanolic extract thereof) to a subject suffering from a cancer (including a tumorous cancer and/or leukemia) based upon the beneficial teachings provided by the primary references with respect to the demonstrated anti-cancer effect such *Curcuma* rhizome extracts provide, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further treat such subjects with light radiation within the claimed nanometer range based upon the beneficial teachings provided by Otsuka et al. with respect to the demonstrated anti-cancer effect such light radiation provides, as discussed above.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah (US 5,693,327) and Bernd et al. (J. Invest. Dermatol., 1997 - KOSMET Meeting Abstract), in view of Wilkens (DE 4440112 - DWPI Abstract).

Shah beneficially teaches a method for treating various conditions associated with a proliferative disease including some of those instantly claimed (e.g., psoriasis and lichen planus) via administering to a subject in need thereof a composition comprising an effective amount of a *Curcuma longa* and/or *Curcuma aromatica* aqueous extract therein (see entire document including col 1, line 4 - col 2, line 55; col 4, line 39 - col 5, line 29; col 7, lines 5-6; and claims).

Bernd et al. beneficially disclose an *in vitro* study demonstrating that an aqueous-alcoholic *Curcuma longa* rhizome extract is effective against proliferative diseases such as those involving increased IL-6 and IL-8 cytokine production including psoriasis (see KOSMET Abstract). Neither Shah nor Bernd et al. teach the further use of radiation for treating such proliferative conditions as psoriasis.

Wilkens beneficially teaches the use of light radiation within the visible light range of 400-800 nanometers to a subject suffering from psoriasis via administering the light radiation to the body of the subject.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer a *Curcuma longa* rhizome extract (including an aqueous and/or ethanolic extract thereof) to a subject suffering from a proliferative disease condition such as psoriasis based upon the beneficial teachings provided by Shah and Bernd et al. with respect to the demonstrated anti-proliferative/anti-psoriasis effect such *Curcuma* rhizome extracts provide, as discussed above. It would also have been obvious to one of ordinary skill in the art at the time the claimed invention was made to further treat such subjects with light radiation within the claimed nanometer range based upon the beneficial teachings provided by Wilkens with respect to the demonstrated anti-psoriasis effect such light radiation provides, as discussed

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above. The adjustment of particular conventional working conditions (e.g., determining an appropriate radiation wavelength within the instantly claimed range - based upon the beneficial teachings provided by Wilkens) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quintanilla Almagro et al. (ES 2103689 - including full English translation thereof).

The cited reference beneficially teaches a method of treating (augmenting) one or more conditions associated with a proliferative disease, such as various cell proliferative diseases/disorders related to skin ageing in a mammal (humans) via administering to the mammal one or more (aqueous and/or ethanolic) extracts from *Curcuma longa* rhizomes (which, as readily admitted by Applicants reads upon the instantly claimed extract - see, e.g., paragraph [0049] of the instant specification) - see entire English translation including pages 9-26, Figures, and claims thereof. Further, again please note that, as drafted, the claims are not limited to a mammal having a condition associated with a proliferative disease, but instead to a mammal susceptible to a condition associated with a proliferative disease. Since mammals including humans are susceptible to one or more conditions associated with a proliferative disease (such as

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those characterized by an increase in cytokine production such as increased IL-8 or IL-6 production, as well as the various conditions recited in claim 12), the administered mammals (humans) disclosed by the cited reference meet this claim limitation - as drafted (including with respect to prophylactic/preventative treatment thereof). The cited reference also beneficially discloses that the administration of such *Curcuma longa* extracts provided UV protection to *in vitro* cell cultures exposed to UV irradiation (see, e.g., pages 14-17 of the English translation).

It would have been obvious to one of ordinary skill in the art to administer one or more *Curcuma longa* extracts such as those disclosed by Quintanilla Almagro et al. to a subject who has been or who would subsequently at some point be exposed to UV irradiation (such as UV rays and/or other visible light radiation from the sun) based upon the beneficial teachings provided by the cited reference with respect to the demonstrated UV protective effect such *Curcuma longa* extracts provide.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### **Conclusion**

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate  
Primary Examiner  
Art Unit 1655